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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OIPE JC188 SEP 2 0 2002 PATENT & TRADEMARK OFFICE

In re application of:
SHERMAN *et al.*
Appl. No.: 09/501,730
Filed: February 10, 2000

Confirmation No. 4303
Art Unit: 1652
Examiner: Pak, Y.D.
Atty. Docket: 2057.0080000/JAG/BJD

#19
DGJ
9/26/02

For: **Aggregate-Free Urate Oxidase for Preparation of Non-Immunogenic Polymer Conjugates**

Declaration Under 37 C.F.R. § 1.132

Commissioner for Patents
Washington, DC 20231

Box AF

Sir:

I, Merry R. Sherman, Ph.D., declare and state that:

1. I am one of the inventors of the subject matter of U.S. Patent Application Serial No. 09/501,730 ("the present application") filed February 10, 2000, which is referenced above.

2. I am also the President of Mountain View Pharmaceuticals, Inc. ("MVP"), the assignee of the present application by virtue of an assignment from all of the inventors to MVP executed on April 26, 2000, and recorded in the U.S. Patent and Trademark Office on May 22, 2000, beginning at Reel No. 010836, Frame No. 0572.

3. My *curriculum vitae* is attached as **Exhibit A**.

4. MVP is the owner of U.S. Trademark Registration No. 2,246,623, for the word mark PURICASE®, which was registered in the Principal Register of the U.S.

Patent and Trademark Office on May 18, 1999. The PURICASE® mark as registered is associated with pharmaceutical preparations containing uricase coupled to polyethylene glycol ("PEG-uricase conjugates") for use in the treatment of hyperuricemia and related conditions. These conjugates are exemplary emodiments that are encompassed by certain claims of the present application.

5. I am familiar with the prosecution history of the present application to date. I would like to address certain remarks raised by Examiner Pak in the Office Action issued May 22, 2002 (Paper No. 14).

6. At page 5 of the Office Action, Examiner Pak states that:

> The owner of Puricase™ is Mountain View Pharmaceuticals, INC., the assignee of the instant invention and Puricase™ was first used in commerce from December 17, 1998 (U.S. Trademark, Registration No. 2,246,623).

7. In support of this statement, Examiner Pak relies upon a printout of a record from the U.S. Trademark Electronic Search System ("the TESS printout"), cited as Doc. No. U1 on the Form PTO-892 attached to a previous Office Action (Paper No. 11), mailed December 5, 2001. In the heading "Goods and Services," this printout indicates that the word mark PURICASE® was first used in commerce on December 17, 1998.

8. The "first use in commerce" for the word mark PURICASE® listed in the TESS printout is based on information provided by MVP in its application to the U.S. Patent and Trademark Office for registration of the word mark PURICASE®. However, this "first use in commerce" does not reflect a sale or public availability of the goods identified by the PURICASE® mark on December 17, 1998. Instead, on that date, personnel of MVP under my

direction and control sent test samples of PEG-uricase conjugates to Sterilization Technical Services ("STS"), a contract testing laboratory in Rush, New York, for pharmacokinetic testing by STS. The samples were sent to STS via Federal Express (Airbill 8056 3147 2683, delivered at 9:55 am, December 18, 1998). This testing was performed under confidentiality and for experimental purposes only, as part of an ongoing research and development program at MVP developing PURICASE® brand of uricase conjugates and compositions. The testing performed by STS was at the request of, under the direction of, and at the expense of MVP. STS injected the samples into mice, collected blood from the mice, from which it prepared serum. The serum samples were shipped back to MVP, where analyses were performed to determine the rate of disappearance of the PEG-uricase from the circulation of the mice. At no time did STS pay MVP for the test samples of PEG-uricase provided by MVP to STS, and MVP did not offer this material for sale to STS or to any other individual or entity on or before December 17, 1998.

9. Therefore, on December 17, 1998, the goods associate with the PURICASE® word mark were transported in interstate commerce, but were not on sale or otherwise in public use, and were not the subject of a commercial offer for sale.

10. I have read, I am familiar with, and I understand the provisions of 37 C.F.R.§§10.18(b) and (c) relating to the effect of signature and certificate for correspondence filed in the U.S. Patent and Trademark Office.

Further, declarant saith not.

September 11, 2002
Date

Merry R. Sherman
Merry R. Sherman, Ph.D.

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MERRY RUBIN SHERMAN, PH.D.
President
Mountain View Pharmaceuticals, Inc.

Education:

Wellesley College, Wellesley, MA	B.A.	1961	Chemistry
University of California, Berkeley, CA	M.A.	1963	Biochemistry
University of California, Berkeley, CA	Ph.D.	1966	Biophysics
Weizmann Institute, Rehovot, Israel	Postdoctoral	1966-1967	Polymer Science
National Institutes of Health, Bethesda, MD	Fellowships	1967-1970	Biochemistry

Research Positions:

1970-1976 Research Associate and Associate, Department of Surgical Research, Sloan-Kettering Institute (SKI), New York, NY
1975-1976 Visiting Investigator, Cardiovascular Research Institute, University of California Medical Center, San Francisco, CA
1975-1986 Head, Endocrine Biochemistry Laboratory, SKI
1/92-8/92 Visiting Scientist, New York University Medical Center, New York, NY
1993-1995 Pharmaceutical Consultant, Mountain View, CA
1995-present President, Mountain View Pharmaceuticals, Inc.

Academic Positions: *Positions at Cornell University Graduate School of Medical Sciences (CUGSMS), New York, NY, were concurrent with those at SKI*

1971-1972 Instructor in Biochemistry, CUGSMS, New York, NY
1972-1977 Assistant Professor of Biochemistry, CUGSMS
1977-1986 Associate Professor of Biochemistry, CUGSMS
1986-1993 Professor of Biochemistry, Rutgers University, Newark, NJ

Honors:

1957 Finalist, National Science Talent Search
1960 Elected to *Phi Beta Kappa*
1985 Outstanding Woman Scientist Award, Association for Women in Science, Metropolitan New York Chapter
1987 Distinguished Alumna Award, New Rochelle High School, New Rochelle, NY

Editorial Boards and Refereeing:

1974-1978 Editorial Board, *Endocrine Research Communications*
7/78-6/81 Editorial Board, *Journal of Biological Chemistry*
7/82-6/84 Editorial Board, *Journal of Biological Chemistry*
Occasional reviews for:
Anal Biochem, Arch Biochem Biophys, Biochemistry, Cancer Research, Endocrinology, Nature, Proc Natl Acad Sci USA, Steroids

Special NIH Study Sections: 2/77, 1/79, 12/82, 5/85 and 4/91

National Committees:

9/84-6/88 Program Committee of The Endocrine Society
12/85-6/88 Board of Scientific Counselors, Natl. Institute of Child Health and Human Dev.

Professional Memberships: American Society of Biological Chemists, The Endocrine Society, American Association for Cancer Research, Society for Neuroscience, Association for Women in Science

Selected Publications:

Rubin MM, Katchalsky A (1966) Mathematics of band centrifugation: Concentration-independent sedimentation and diffusion in shallow density gradients. Biopolymers 4:579-593.

Rubin MM, Changeux J-P (1966) On the nature of allosteric transitions: Implications of non-exclusive ligand binding. J Mol Biol 21:265-274.

Changeux J-P, Rubin MM (1968) Allosteric interactions in aspartate transcarbamylase. III. Interpretation of experimental data in terms of the model of Monod, Wyman and Changeux. Biochemistry 7:553-561.

Rubin MM, Piez KA, Katchalsky A (1969) Equilibrium mechanochemistry of collagen fibers. Biochemistry 8:3628-3637.

O'Malley BW, Sherman MR, Toft DO (1970) Progesterone "receptors" in the cytoplasm and nucleus of chick oviduct target tissue. Proc Natl Acad Sci USA 67:501-508.

Sherman MR, Corvol PG, O'Malley BW (1970) Progesterone-binding components of chick oviduct. I. Preliminary characterization of cytoplasmic components. J Biol Chem 245:6085-6096.

O'Malley BW, Toft DO, Sherman MR (1971) Progesterone-binding components of chick oviduct. II. Nuclear components. J Biol Chem 246:1117-1122.

Sherman MR, Atienza SBP, Shansky JR, Hoffman LM (1974) Progesterone receptors of chick oviduct. Steroid-binding "subunit" formed with divalent cations. J Biol Chem 249:5351-5363.

Sherman MR (1975) Physical-chemical analysis of steroid hormone receptors. Methods Enzymol 36:211-234.

Bullock LP, Bardin CW, Sherman MR (1978) Androgenic, antiandrogenic and synandrogenic actions of progestins: Role of steric and allosteric interactions with androgen receptors. Endocrinology 103:1768-1782.

Sherman MR, Pickering LA, Rollwagen FM, Miller LK (1978) Mero-receptors: Proteolytic fragments of receptors containing the steroid-binding site. Fed Proc 37:167-173.

Sherman MR, Tuazon FB, Miller LK (1980) Estrogen receptor cleavage and plasminogen activation by enzymes in human breast tumor cytosol. Endocrinology 106:1715-1727.

Sherman MR, Moran MC, Tuazon FB, Stevens Y-W (1983) Structure, dissociation, and proteolysis of mammalian steroid receptors. Multiplicity of glucocorticoid receptor forms and proteolytic enzymes in rat liver and kidney cytosols. J Biol Chem 258:10366-10377.

Sherman MR, Tuazon FB, Stevens Y-W, Niu E-M (1983) Oligomeric steroid receptor forms and the products of their dissociation and proteolysis. *in:* Steroid Hormone Receptors: Structure and Function, Proceedings of the 57th Nobel Symposium, Karlskoga, Sweden, 1983, (Eriksson H, Gustafsson J-A, *eds.*). Amsterdam, Elsevier, pp. 3-24.

Sherman MR, Stevens Y-W, Tuazon FB (1984) Multiple forms and fragments of cytosolic glucocorticoid receptors from human leukemic cells and normal lymphocytes. Cancer Research 44:3783-3796.

Sherman MR, Stevens J (1984) Structure of mammalian steroid receptors: Evolving concepts and methodological developments. Annu Rev Physiol 46:83-105.

Gorsline J, Bradlow HL, Sherman MR (1985) Triamcinolone acetonide 21-oic acid methyl ester: A potent local antiinflammatory steroid without detectable systemic effects. Endocrinology 116:263-273.

Maayani S, Sherman MR (1990) Adenylate cyclase-linked 5-hydroxytryptamine receptors in the brain. *in:* Serotonin: From Cell Biology to Pharmacology and Therapeutics, (Paoletti R, Vanhoutte PM, Brunello N, Maggi FM, *eds.*). Dordrecht, The Netherlands, Kluwer Academic Publishers, pp. 39-51.

Smith RA, Balis FM, Ott KH, Elsberry DD, Sherman MR, Saifer MGP (1995) Pharmacokinetics and tolerability of ventricularly administered superoxide dismutase in monkeys and preliminary clinical observations in familial ALS. J Neurol Sci 129 (Suppl):13-18.

Saifer MGP, Williams LD, Sherman MR, French JA, Kwak LW, Oppenheim JJ (1997) Improved conjugation of cytokines using high molecular weight poly(ethylene glycol): PEG-GM-CSF as a prototype. Polymer Preprints 38:576-577.

Sherman MR, Williams LD, Saifer MGP, French JA, Kwak LW, Oppenheim JJ (1997) Conjugation of high molecular weight poly(ethylene glycol) to cytokines: Granulocyte-macrophage colony-stimulating factors as model substrates. *in:* Poly(ethylene glycol) Chemistry and Biological Applications. ACS Symposium Series 680, (Harris JM, Zalipsky S, *eds.*). Washington, DC, American Chemical Society, pp. 155-169.